GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

STARRED QUESTION NO:139
ANSWERED ON:27.11.2001
NATIONAL DRUG AUTHORITY
SULTAN SALAHUDDIN OWAISI

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that formation of the National Drug Authority was first recommended by Hathi Committee a long back ;

(b) if so, whether it is also a fact that this Authority has not seen light of the day ;

(c) if so, the main reasons therefor :

(d) whether various organisations / manufacturers / experts have expressed their views for the urgent need to establish the National Drug Authority on priority basis ;

(e) if so, the details in this regard ;

(f) whether the Government propose to set up National Drug Authority for better monitoring the quality control and rational use of drugs ;

(g) if so, the time by which it is likely to be set up ; and

(h) if not , the reasons therefor ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI S.B. MOOKHERJEE)

(a) to (h) : A statement is laid on the Table of the House.

STATEMENT REFERRED IN ANSWER TO PARTS (a) to (h) OF THE LOK SABHA STARRED QUESTION NO. 139 FOR ANSWER ON 27.11.2001

(a) to (c): The (Hathi) Committee on Drugs and Pharmaceuticals Industry, in its report submitted in April,1975, had, interalia, recommended the setting up of a National Drug Authority - an autonomous body which would handle all matters concerning the future expansion of the drug industry licensing, imports, exports technological development. Government laid a Statement on the Table of the Lok Sabha on 29.3.1978 containing its decisions on the said recommendations (later known as Drug Policy,1978) wherein it was concluded that it would not be possible to establish a totally independent authority on the lines suggested by the Committee. However, it was approved to set up a field organisation in the Department of Chemicals & Fertilizers under a Development Commissioner (Drug Industry).

(d) to (h) : The Government reviewed the Drug Policy,1978 and restructured it in 1986 by announcing `Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceutical Industry in India` which, interlaia, envisaged setting up of a machinery to be called the National Drug and Pharmaceuticals Authority to look after the rational use of drugs. The importance of quality control and rational use of drugs was reiterated in the `Modifications in Drug Policy,1986` , announced in September,1994 and it was envisaged therein that a National Drug Authority be set up to undertake the regulatory functions performed by the Central Drugs Standard Control Organisation (CDSCO) in addition to assuming many new responsibilities. This, interalia, required major structural changes in the existing regulatory system, where licensing of manufacturers etc. as well as enforcement of the Drugs & Cosmetics Act,1940 and Rules made thereunder, are primarily done by the state authorities. Efforts are being made to strengthen the existing capacity of the Central Drugs Standard Control Organisation (CDSCO) which would be necessary before undertaking the new responsibilities. Hence no time frame can be fixed for setting up of the National Drug Authority.